

Approval Date: JUN - 6 2002

**FREEDOM OF INFORMATION SUMMARY**

**SUPPLEMENTAL NEW ANIMAL DRUG  
APPLICATION**

**NADA 140-863**

**Ractopamine hydrochloride (PAYLEAN®)**

**For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.**

**Sponsored by:**

**Elanco Animal Health  
A Division of Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana 46285**

*NADA 140-863*

*FOIS 1*

## **FREEDOM OF INFORMATION SUMMARY**

Purpose of supplement: To amend cautionary language in product labeling

### **I. GENERAL INFORMATION:**

NADA Number: 140-863

Sponsor: Elanco Animal Health  
A Division of Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana 46285

Generic Name: Ractopamine hydrochloride

Trade Name: Paylean®

Marketing Status: Over the Counter (OTC)

### **II. INDICATIONS FOR USE:**

For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

### **III. DOSAGE:**

- a. Dosage Form: Paylean® Type A Medicated Article is available as a 25-pound bag containing 9 or 45 grams of ractopamine hydrochloride per pound.
- b. Route of Administration: Oral, via the feed
- c. Recommended Dosage:

Ractopamine hydrochloride should be fed at a concentration of 4.5 g of ractopamine hydrochloride per ton of complete feed (5 ppm) for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in a ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

Ractopamine hydrochloride should be fed at a concentration of 4.5 g to 18 g of ractopamine hydrochloride per ton of complete feed (5 ppm to 20 ppm) for improved feed efficiency and increased carcass leanness in a ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

**ELANCO****AF0602-25B****For Use in Finishing  
Swine Feeds Only****Paylean<sup>®</sup> 45****Ractopamine  
Hydrochloride**

\*

**Net Weight 25 lb  
(11.34 kg)****Type A Medicated Article**

Do not feed undiluted.
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**Active Drug Ingredient:** ractopamine hydrochloride – 45.4 g per lb (100 g per kg)**Important:** Must be thoroughly mixed into feeds before use. Follow label directions.**Indication:** For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

Indications	Appropriate Concentration of Ractopamine in Type C Medicated Feed
Increased Rate of Weight Gain, Improved Feed Efficiency, and Increased Carcass Leanness	4.5 grams/ton (5 ppm)
Improved Feed Efficiency and Increased Carcass Leanness	4.5 to 18 grams/ton (5 ppm to 20 ppm)

**Inert Ingredients:** Ground corncobs.

Carcass Measurements	Effect of Ractopamine	
	4.5 grams/ton (5 ppm)	9 - 18 grams/ton (10 - 20 ppm)
Carcass Fat	NC	↓
10th Rib Backfat (3/4 location)	NC	↓
Last Rib Backfat (midline)	NC	NC
Loineye Area (10th rib)	NC	↑
Rate of Lean Gain	NC	↑
Efficiency of Lean Gain	NC	↑
Dressing Percentage	NC	↑

NC= No Change, ↑ = increased, ↓ = decreased

**Mixing Directions:** Thoroughly mix Paylean 45 Type A Medicated Article into one ton of appropriate feed ingredients or diluents according to the table below to obtain the proper concentration in the Type B Medicated Feed (maximum 3600 g/ton). The following table gives examples of how some Type B Medicated Feed concentrations can be prepared:

Pounds of Paylean 45 To Add Per Ton To Make a Type B Medicated Feed	Resulting Ractopamine Concentration in Type B Medicated Feed	
	grams/ton	grams/pound
19.82	900	0.45
39.65	1,800	0.90
59.47	2,700	1.35
79.30	3,600	1.80

Thoroughly mix Paylean 45 Type A Medicated Article into one ton of complete swine feed according to the table below to obtain the proper concentration in the Type C Medicated Feed. Prepare at least one intermediate pre-blend of the premix prior to mixing in a complete feed. Thoroughly mix the required amount in a convenient quantity of feed ingredients then add to the remaining feed ingredients to make a ton of complete feed.

Pounds Paylean 45 To Add Per Ton of Type C Medicated Feed	Resulting Ractopamine Concentration in Type C Medicated Feed	
0.10	4.5	grams/ton ( 5 ppm)
0.20	9	grams/ton (10 ppm)
0.30	13.5	grams/ton (15 ppm)
0.40	18	grams/ton (20 ppm)

**Feeding Directions:** Feed continuously to finishing swine as the sole ration from 150 lb (68 kg) to 240 lb (109 kg) body weight.

**CAUTION:** Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean. Not for use in breeding swine.

**WARNING:** The active ingredient in Paylean, ractopamine hydrochloride, is a beta-adrenergic agonist. Individuals with cardiovascular disease should exercise special caution to avoid exposure. Not for use in humans. Keep out of the reach of children. The Paylean 9 formulation (Type A Medicated Article) poses a low dust potential under usual conditions of handling and mixing. When mixing and handling Paylean, use protective clothing, impervious gloves, protective eye wear, and a NIOSH-approved dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse eyes thoroughly with water. If irritation persists, seek medical attention. The material safety data sheet contains more detailed occupational safety information. To report adverse effects, access medical information, or obtain additional product information, call 1-800-428-4441.

Store at room temperature.

Expiration Date and Lot Number are printed on the bag. Not to be used after the expiry date.

## Paylean® 45

Elanco Animal Health  
A Division of Eli Lilly and Company  
Indianapolis, IN 46285, U.S.A.



Questions or Comments: Call 1-800-428-4441

\*Elanco®, Paylean®, and the diagonal color bar are trademarks of Eli Lilly and Company

Revised 9/20/01

Net Weight lb (kg) on bag or bulk

**Paylean® Finishing Swine Feed**  
**Type C Medicated Feed**

For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

**ACTIVE DRUG INGREDIENT**

Ractopamine hydrochloride..... 4.5 g/ton

**GUARANTEED ANALYSIS**

Crude Protein, not less than.....	16.00 %
Lysine, not less than.....	%
Crude Fat, not less than.....	%
Crude Fiber, not more than.....	%
Calcium, not less than.....	%
Calcium, not more than.....	%
Phosphorus, not less than.....	%
Salt <sup>1</sup> , not less than.....	%
Salt <sup>1</sup> , not more than.....	%
Sodium <sup>2</sup> , not less than.....	%
Sodium <sup>2</sup> , not more than.....	%
Selenium, not less than.....	ppm
Zinc, not less than.....	ppm

<sup>1</sup>If added.

<sup>2</sup>Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

**DIRECTIONS FOR USE**

Feed continuously to finishing swine as the sole ration from 150 lb (68 kg) to 240 lb (109 kg) body weight.

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**CAUTION:** Pigs fed Paylean are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of Paylean. Not for use in breeding swine.

**MANUFACTURED BY**

**BLUE BIRD FEED MILL**  
Any town, USA 12345

Paylean® is a registered trademark of Eli Lilly and Company.

Net Weight lb (kg) on bag or bulk

# Paylean® Finishing Swine Feed

## Type C Medicated Feed

For improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.

### ACTIVE DRUG INGREDIENT

Ractopamine hydrochloride..... 4.5 to 18 g/ton

### GUARANTEED ANALYSIS

Crude Protein, not less than.....	16.00 %
Lysine, not less than.....	%
Crude Fat, not less than.....	%
Crude Fiber, not more than.....	%
Calcium, not less than.....	%
Calcium, not more than.....	%
Phosphorus, not less than.....	%
Salt <sup>1</sup> , not less than.....	%
Salt <sup>1</sup> , not more than.....	%
Sodium <sup>2</sup> , not less than.....	%
Sodium <sup>2</sup> , not more than.....	%
Selenium, not less than.....	ppm
Zinc, not less than.....	ppm

<sup>1</sup>If added.

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